School of Dentistry Moderate (Conscious) Sedation Policy

**Definitions**
Moderate (conscious) sedation or analgesia is a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.

Deep sedation or analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

*Reflex withdrawal from a painful stimulus is not considered a purposeful response.

**Sources**
This policy includes stipulations from *Dental Rules of North Carolina State Board of Dental Examiners (2008)* and *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologist: American Society of Anesthesiologists (2002)* since both should guide the practice of anesthesia in any setting. Additional provisions that are specific to periodontology or pediatric dentistry are based on *Guidelines: In-Office Use of Conscious Sedation in Periodontics: American Academy of Periodontology (2001)* and *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update: American Academy of Pediatrics and American Academy of Pediatric Dentistry (2006).* The applicable *Dental Rules of North Carolina State Board of Dental Examiners* are appended to the end of this document.

**Facility**
Treatment room shall have a size and design that permits access of emergency equipment and personnel to permit effective emergency management, and contain:

- A chair suitable for CPR or CPR board must be present
- Lighting as necessary for specific procedures must be present
- Suction equipment as necessary for specific procedures, including non-electrical back-up suction must be available

**Equipment**
The following must be maintained:

- Positive pressure oxygen delivery system, including full face mask for adults and pediatric patients
- Oral and nasal airways of various sizes
- Blood pressure monitoring device
- Pulse oximeter

**Emergency Equipment**
Must maintain IV hardware and fluids including

- Syringes as necessary for specific procedures
- Tourniquet
- Tape

Approved by Department Chairs Committee 5/4/11
● Alcohol wipes
● Sterile gauze pads
● Intravenous catheters (24-22 gauge)
● Intravenous tubing
● Intravenous fluid
● Syringes and assorted needles for drug aspiration and intramuscular injection

**Drugs**
Drugs are maintained with a current shelf life and with easy accessibility from the operatory and recovery area, and include:
● Epinephrine
● Atropine
● Antiarrythmic
● Narcotic antagonist
● Antihistamine
● Corticosteroid
● Nitroglycerine
● Bronchial dilator
● Antiemetic
● Benzo antagonist
● Muscle relaxant for intubation
● 50% Dextrose
● Ephedrine (not required in Pediatric Dentistry)
● Vasopressin (not required in Pediatric Dentistry)
● Benzodiazepine

**Written Protocols and Training**
Written emergency protocols must be maintained and training must be provided to familiarize office personnel in the treatment of clinical emergencies.

**Pre-operative Evaluation**
● Patient’s current written medical history, including known allergies and previous surgery must be reviewed.
● For ASA III patients, consultation with patient’s primary care physician is recommended.
● Must consider how patient’s medical history might alter patient’s response to sedation, including:
  ○ Abnormalities of the major organ systems
  ○ Previous adverse experience with sedation as well as regional and general anesthesia
  ○ Drug allergies, current medications, and potential drug interactions
  ○ Time and nature of last oral intake
  ○ History of tobacco, alcohol, or substance use or abuse
● Focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway.
● Patients undergoing sedation or anesthesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure, as recommended by the ASA “Guidelines for Preoperative Fasting” ingested material minimum fasting period:
  ○ Clear liquids 2 hours
Approval by Department Chairs Committee 5/4/11

- Nonhuman milk 6 hours
- Light meal 6 hours

**Faculty Supervision**
- The use of IV sedation must be approved by attending faculty
- Faculty must be present in the clinic throughout the procedure

**Monitoring**
- **Patient response to verbal commands** should be routine during moderate sedation.
- **Oxygenation** should be monitored by pulse oximetry with appropriate alarms.
- **Ventilatory function** should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. In Periodontics clinic, breath sounds should be auscultated.
- **Blood pressure** should be determined before sedation or analgesia is initiated. Once sedation or analgesia is established, blood pressure should be measured at 5-minute intervals during the procedure, unless such monitoring interferes with the procedure.
  - Periodontics clinic-Blood pressure and HR must be continually monitored.
  - Pediatric clinic-Pre-op and intra-op vital signs, including SpO2, HR (continuous) and Bp (intermittent) shall be monitored and recorded on a time-based record. It is noted that for some children who are very upset or noncooperative, this may not be possible; in such cases this should be documented in the patient record.
- **Electrocardiographic monitoring** should be used on
  - patients undergoing deep sedation (which should be restricted to OMFS)
  - patients undergoing moderate sedation with significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

**Records**
A sedation record shall be maintained that includes:
- time-oriented anesthesia record including recordings, at a minimum, from before the start of the procedure, after administration of sedative-analgesic agents, at regular intervals during the procedure, during initial recovery, and just before discharge
- drugs administered during the procedure, including route of administration, dosage, time and sequence of administration
- blood pressure
- pulse rate
- respiration (ventilator and oxygenation status)
- level of consciousness
- hemodynamic variables assessed and recorded at a frequency dependent on the type and amount of medication administered, the length of the procedure, and the general condition of the patient.
- duration of procedure
- complications or morbidity
- status of patient upon discharge
- Records must be signed by the supervising faculty
**Personnel**

- Staff, residents and faculty must be Basic Life Support certified and capable of assisting with procedures, problems, and emergency incidents.
- Supervising faculty must hold an active North Carolina sedation permit and satisfy all requirements for that permit, including certification in Basic Life Support annually.
- During moderate sedation, a designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation. This individual may assist with minor, interruptible tasks once the patient’s level of sedation-analgesia and vital signs have stabilized, provided that adequate monitoring for the patient’s level of sedation is maintained.
- During deep sedation (restricted to OMFS), a designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation. This individual should have no other responsibilities.
- Training of personnel shall include:
  - Individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines.
  - Individuals monitoring patients receiving sedation-analgesia should be able to recognize the associated complications.
  - At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means of summoning additional assistance, should be present whenever sedation-analgesia is administered.
  - It is recommended that an individual with advanced life support skills be immediately available (within 5 minutes) for moderate sedation and within the procedure room for deep sedation.
- In the Periodontics clinic, minimum personnel include a periodontist and a dental assistant, who is trained to monitor and assist in resuscitation and is BLS certified.

**Propofol, Methohexital, Ketamine**

- Even if moderate sedation is intended, patients receiving propofol, methohexital, or ketamine by any route require care consistent with that required for deep sedation. Accordingly, practitioners administering these drugs should be qualified to rescue patients from any level of sedation, including general anesthesia.
- **Hence, these drugs should only be used in the OMFS clinic.**

**Recovery and Discharge Criteria after Sedation and Analgesia**

- Medical supervision of recovery and discharge is the responsibility of the operating practitioner.
- The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
- Patients should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation-analgesia was administered.
  - Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
  - Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
An individual trained to monitor patients and recognize complications should be present until discharge criteria are fulfilled.

An individual capable of managing complications should be immediately available until discharge criteria are fulfilled.

Guidelines for discharge:
- Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should be returned to their baseline status. Practitioners and parents should be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.
- Vital signs should be stable and within acceptable limits
- Use of scoring systems may assist in documentation of fitness for discharge.
- Sufficient time (up to 2 hours) should have elapsed after the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
- Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
- Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

Authors
Dr. Jay Anderson, Oral and Maxillofacial Surgery
Dr. George Blakey, Oral and Maxillofacial Surgery
Dr. Nadine Brodala, Periodontology
Dr. Michael Milano, Pediatric Dentistry
Dr. Douglas Solow, Diagnostic Sciences and General Dentistry, Clinical Affairs
21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

(a) General anesthesia and all sedation permits shall be renewed by the Board annually. Such renewal shall be accomplished in conjunction with the license renewal process, and applications for permits shall be made at the same time as applications for renewal of licenses. A one hundred ($100.00) annual renewal fee shall be paid at the time of renewal.

(b) All sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued administration of general anesthesia or any level of conscious sedation shall be unlawful and subject the dentist to the penalties prescribed by Section .0700 of this Subchapter.

(c) As a condition for renewal of the general anesthesia permit, the permit holder shall meet the requirements of 21 NCAC 16Q .0202 and document current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.

(d) As a condition for renewal of the moderate conscious sedation permit or moderate pediatric conscious sedation permit, the permit holder shall meet the requirements of 21 NCAC 16Q .0302 and the following criteria:

(1) document annual, successful completion of BLS training and obtain three hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:
   (A) sedation;
   (B) medical emergencies;
   (C) monitoring IV sedation and the use of monitoring equipment;
   (D) pharmacology of drugs and agents used in IV sedation;
   (E) physical evaluation, risk assessment, or behavioral management; or
   (F) audit ACLS/Pediatric Advanced Life Support (PALS) courses.

(2) document current, successful completion of ACLS training or its age-specific equivalent, or other equivalent course and annual successful completion of BLS; and

(3) moderate pediatric conscious sedation permit holders must have current PALS at all times.

(e) As a condition for renewal of the minimal conscious sedation permit and the moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation, the permit holder shall meet the requirements of 16Q .0402 and shall document annual, successful completion of BLS training and obtain six hours of continuing education every two years in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:

(1) pediatric or adult sedation;
(2) medical emergencies;
(3) monitoring sedation and the use of monitoring equipment;
(4) pharmacology of drugs and agents used in sedation;
(5) physical evaluation, risk assessment, or behavioral management; or
(6) audit ACLS/PALS courses.

(f) Any dentist who fails to renew a general anesthesia or sedation permit on or before March 31 of each year must complete a reinstatement application, pay the one hundred dollar ($100.00) renewal fee and a one hundred dollar ($100.00) penalty and comply with all conditions for renewal set out in this Rule for the permit sought. Dentists whose anesthesia or sedation permits have been lapsed for more than 12 calendar months must pass a facilities inspection as part of the reinstatement process.

History Note: Authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Amended Eff. August 1, 2002;
Transferred and Recodified from 16Q .0401 to 16Q .0501;
Temporary Amendment Eff. December 11, 2002;
21 NCAC 16Q .0502 PAYMENT OF FEES
A fee of fifty dollars ($50.00) shall accompany the permit renewal application, such fee to be separate and apart from the annual license renewal fee imposed by the Board.

History Note: Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0402 to .0502.

21 NCAC 16Q .0503 INSPECTION AUTHORIZED
Incident to the renewal of an anesthesia or sedation permit, for cause or routinely at reasonable time intervals in order to ensure compliance, the Board may require an on-site inspection of the dentist's facility, equipment, personnel and procedures. Such inspection shall be conducted in accordance with Rules .0204, .0205, .0303, and .0401 of this Subchapter.

History Note: Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Amended Eff. January 1, 1994;
Transferred and Recodified from 16Q .0403 to 16Q .0503;
Temporary Amendment Eff. December 11, 2002;

SECTION .0600 - REPORTING AND PENALTIES

21 NCAC 16Q .0601 REPORTS OF ADVERSE OCCURRENCES
(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit a report to the Board within 72 hours after each adverse occurrence related to the administration of general anesthesia or sedation which results in the death of a patient within 24 hours of the procedure.
(b) A dentist who holds a permit to administer general anesthesia or sedation shall report to the Board, within 30 days after each adverse occurrence related to the administration of general anesthesia or sedation, any situation which results in permanent organic brain dysfunction of a patient within 24 hours of the procedure or which results in physical injury causing hospitalization of a patient within 24 hours of the procedure.
(c) The adverse occurrence report shall be in writing and shall include:
   (1) The dentist’s name, license number and permit number;
   (2) The date and time of the occurrence;
   (3) The facility where the occurrence took place;
   (4) The name and address of the patient;
   (5) The surgical procedure involved;
   (6) The type and dosage of sedation or anesthesia utilized in the procedure; and
   (7) The circumstances involved in the occurrence.
(d) Upon receipt of any such report, the Board shall make such investigation as it deems appropriate and shall take such action as it deems necessary.

History Note: Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0501 to 16Q .0601.

21 NCAC 16Q .0602 FAILURE TO REPORT
If a dentist fails to report any incident as required by these Rules, the dentist shall be subject to discipline in accordance with Section .0700 of this Subchapter.

History Note: Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0502 to 16Q .0602;
Temporary Amendment Eff. December 11, 2002;
SECTION .0700 - PENALTY FOR NON-COMPLIANCE

21 NCAC 16Q .0701 FAILURE TO COMPLY
Failure to comply with the provisions of this Subchapter may result in suspension or revocation of the permit and/or the dentist's license to practice dentistry in accordance with G.S. 90-41.

History Note:    Authority G.S. 90-28; 90-30.1; 90-41;
    Eff. February 1, 1990;
    Transferred and Recodified from 16Q .0601 to 16Q .0701.